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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,125

07/31/2007

David James

42-000500US

6581

22798

7590

06/09/2009

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

P O BOX 458

ALAMEDA, CA 94501

EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,125	<b>Applicant(s)</b> JAMES ET AL.	
	<b>Examiner</b> G. R. Ewoldt, Ph.D.	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,24-39,44-47,72-76,97,113-115 and 126-145 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,24-39,44-47,72-76,97,113-115 and 126-145 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### 1. REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), an international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

2. Restriction is required under 35 U.S.C. 121 and 372.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

I. Claim 1, drawn to a method of identifying a compound that reduces whole body insulin sensitivity employing an animal, tissue, or cell having reduced Cbl expression.

II. Claims 24-39, 41, 44-47, and 72-76, drawn to a method of identifying a compound that enhances whole body insulin sensitivity employing an animal, tissue, or cell expressing Cbl.

III. Claim 97 and 113, drawn to a method of identifying a therapeutic target for the treatment of aberrant insulin expression comprising administering to an animal, tissue, or cell a compound capable of reducing Cbl expression or activity.

IV. Claims 114 and 126-129, drawn to a method of identifying a compound that enhances free fatty acid synthesis or reduces (i)-(v) of Claim 114 comprising determining the level of Cbl expression or activity in the presence or absence of the compound.

V. Claims 115 and 130-133, drawn to a method of identifying a compound that reduces free fatty acid synthesis or reduces (i)-(v) of Claim 114 comprising determining the level of

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Cbl expression or activity in the presence or absence of the compound.

VI. Claims 134-138, drawn to a method of identifying a compound that enhances insulin sensitivity comprising determining the level of Cbl expression or activity in the presence or absence of the compound.

VII. Claims 139-143, drawn to a method of identifying a compound that reduces insulin sensitivity comprising determining the level of Cbl expression or activity in the presence or absence of the compound.

VIII. Claims 144 and 145, drawn to a method of treatment of a condition associated with aberrant insulin action comprising administering a compound that modulates ACC, AMPK, FAA, Cbl or fatty acid oxidation.

4. The inventions listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Abu-Heleiga et al. (9/2003, IDS) teaches that ACC2 deficient mice have a higher fatty acid oxidation rate and accumulate less fat. When fed a high fat diet the mice maintained normal levels of insulin and glucose whereas normal mice became type 2 diabetic with hyperglycemia and hyperinsulinemia. The authors go on to teach that ACC2 inhibitors could be used in anti-type 2 diabetes therapies (see particularly the last sentence of the reference). Thus, the prior art teaches the method of Claims 144 and 145.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not comprise a single general inventive concept and lack unity of invention.

5. Accordingly, Groups I-VIII are not so linked as to form a single general inventive concept and restriction is proper.

6. **Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

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7. This application further contains claims directed to the following patentably distinct species: (i)-(xii) of groups I and II, (i)-(v) of groups IV and V.

Should Applicant elect Group I or II for examination Applicant is further required to elect:

A) a specific method of determining a Cbl-associated phenotype such as one of said methods as set forth in (i)-(xii) of Claims 1 or 24.

Applicant is further required to list all claims which read upon the elected species. Currently Claims 1 and 24 are generic.

Should Applicant elect Group IV or V for examination Applicant is further required to elect:

A) a specific method of determining enhancement of reduction of fatty acid synthesis such as one of said methods as set forth in (i)-(v) of Claims 114 or 115.

Applicant is further required to list all claims which read upon the elected species. Currently Claims 114 and 115 are generic.

**8. Applicant is advised that if any of Groups I, II, IV, or V should be elected, the reply to this requirement to be complete must include an election of species to be examined even though the requirement be traversed (37 CFR 1.143).**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0878.

**10. Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information

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about the PAIR system, see <http://pair-direct.uspto.gov>.  
Should you have questions on access to the Private PAIR system,  
contact the Electronic Business Center (EBC) at 866-217-9197.

/G.R. Ewoldt/  
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